AD_____

Award Number: W81XWH-08-2-0206

TITLE: Utilization of Telehealth Technology to Develop and Implement a Comprehensive Management Initiative for Chronic Diseases

PRINCIPAL INVESTIGATOR: Robert A. Vigersky, COL MC, M.D.

CONTRACTING ORGANIZATION: The Henry M Jackson Foundation for the Advancement of Military Medicine
Rockville, MD 20852

REPORT DATE: October 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
October 2011	Annual	22 September 2010 – 21 September 2011

4. TITLE AND SUBTITLE

Utilization of Telehealth Technology to Develop and Implement a Comprehensive Management Initiative for Chronic Diseases

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-08-2-0206

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Robert A. Vigersky, COL MC, M.D.

E-Mail: gay.hayden@amedd.army.mil

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The Henry M Jackson Foundation for the Advancement of Military Medicine
Rockville, MD 20852

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Chronic diseases affect over 90 million Americans and result in high health care costs and tremendous personal and societal burden. Diabetes is, arguably, among the most pervasive and researched chronic diseases. Research shows that much of the costs and burden of diabetes can be mitigated with appropriate education, care- and self-management. This project, called the Comprehensive Management for Chronic Disease (CMICD), focuses on innovative technology approaches to improving education about and management of diabetes. The CMICD includes: virtual education techniques for training nurses (VNE); an Internet-based medical informatics tool for the management of people with diabetes called the Comprehensive Diabetes Management Program (CDMP) and its associated telehealth eye care program that can remotely evaluate eye disease without need of dilation or a specialist to conduct a live exam; a video cell phone approach to providing patients with daily, personalized reminders and education; and a computer-assisted decision support (CADS) tool that equips primary care providers with the latest clinical guidelines and specialty expertise to support their decision making about diabetes, hypertension, and hyperlipidemia. Components of the CMICD are being developed and evaluated for accuracy and usability as part of this effort (CADS), other components are being deployed and tested in rural PA in collaboration with Mt. Aloysius College (VNE and CDMP/telehealth eye care program), and others are being deployed and tested at Walter Reed Health Care System (Cell Phone). Using a variety of study designs, this project is examining both patient outcomes and providers' changes in knowledge as appropriate. Currently the CMICD focuses on the management of diabetes; however, the management approaches within the CMICD are applicable to a variety of other chronic diseases including asthma, depression, and arthritis. This Annual Report presents progress and challenges to date as well as some findings.

15. SUBJECT TERMS
Telemedicine, diabetes, technology, care-management, decision support, nursing education

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	17	**19b. TELEPHONE NUMBER** *(include area code)*

Table of Contents

Page

Introduction

Diabetes mellitus (DM) affects approximately 24 million people in the United States (Centers for Disease Control, 2005) and is associated with devastating complications in both personal and financial terms. Diabetes is the leading cause of blindness, non-traumatic amputations, and renal failure in adults and reduces life expectancy by 5-10 years. The direct ($153 billion) and indirect ($65 billion) costs of DM care have dramatically increased along with the epidemic increase in the number of those with DM over the past 10 years (Centers for Disease Control and Prevention, 2008; PharmaLive.com, accessed 14January2010). The vast majority of these costs are related to hospitalizations resulting from the chronic complications of diabetes, with only about 15% of the costs attributable to professional visits and pharmaceuticals. Much of the costs and burden of diabetes can be mitigated with appropriate education, care, and self-management. This project, a collaboration among Walter Reed Army Medical Center (WRAMC), Mount Aloysius College, and the Henry M. Jackson Foundation, is deploying and testing an innovative, technologically sophisticated program for managing and improving outcomes of diabetes. The program is called the Comprehensive Management Initiative for Chronic Disease (CMICD) and includes the following: a) virtual education techniques for training nurses (VNE); b) a video cell phone approach to providing patients with daily, personalized reminders and education; c) an Internet-based medical informatics tool for the management of people with diabetes called the Comprehensive Diabetes Management Program (CDMP) and its associated telehealth eye care program that can remotely evaluate eye disease without need of dilation or a specialist to conduct a live exam; and d) a computer-assisted decision support (CADS) tool that equips primary care providers with the latest clinical guidelines and specialty expertise to support their decision making about diabetes, hypertension, and hyperlipidemia. Components of the CMICD are being developed and evaluated for accuracy and usability as part of this effort (CADS), other components are being deployed and tested in rural PA in collaboration with Mt. Aloysius College (VNE and CDMP/telehealth eye care program), and others are being deployed and tested at Walter Reed Health Care System (Cell Phone). Using a variety of study designs, this project is examining both patient outcomes and providers' changes in knowledge as appropriate. Although the CMICD focuses on the management of diabetes, the management approaches within the CMICD are applicable to a variety of other chronic diseases including asthma, depression, and arthritis. Currently the overall project and its components are ongoing. This report describes our progress to date based on the original Statement of Work and our plans for the following year.

Body

a. Task/objective regarding Virtual Education Techniques -- to determine whether the use of virtual education techniques can improve diabetes knowledge for practicing registered nurses as well as student nurses

The increased incidence and prevalence of diabetes in rural areas of west-central Pennsylvania, coupled with the scarcity of certified diabetes educators in this geographic location, threatens to become a major public health concern. One response to this growing crisis would be to provide continuing, high quality diabetes education for nurses who care for patients with diabetes in a variety of in-patient and out-patient settings. Such education is often less accessible to nurses who live and practice in rural areas, where distance and time present formidable barriers to educational access. Virtual diabetes education techniques that combine best educational practices with telehealth technology offer a promising solution to this problem.

We have completed this task/objective. Specifically, we:

1) Drafted a study protocol to evaluate the effectiveness of and satisfaction with virtual diabetes nursing education techniques compared to the effectiveness of and satisfaction with traditional, face-to-face, classroom-based diabetes nursing education. The protocol was approved by the local and federal IRBs. The study design was that of a quasi-experimental design (i.e., nonrandom assignment) with two groups -- half received the in-person training and half received a web-based version. Specifically, traditional

diabetes education for nurses taught by certified diabetes educators and clinicians and offered on-site at the Walter Reed Army Medical Center (WRAMC) was made available in a web-based format to registered nurses in a rural area of west-central Pennsylvania (PA). Certain lectures were also provided via video-teleconference to facilitate communication between the students in rural PA with the instructors in Washington, DC, and to integrate the PA students into the course. Effectiveness was measured as change (improvement) in diabetes knowledge and nursing skill as measured by pre- and post-class questionnaires. Satisfaction with the education delivery methods was measured using validated questionnaires. Statistical analyses examined whether there were within and between group differences in learning outcomes and satisfaction.

2) Created and uploaded all course content to a secure web site available only to the PA students. The course content was divided into 'modules' (by lecture) and was synchronized with the "live" lectures delivered by the instructors. After each module, the web site interactively "quizzed" the students on the material presented. We also videotaped a "live" examination of a patient with diabetes by a Nurse Practitioner of the Diabetes Institute at WRAMC, and made this available on the web site.

3) We held three Nurses Workshops in which we enrolled 24 nurses at the WRAMC site and 32 at the rural PA site.

4) We analyzed the data collected from the workshops and found:

i) Students preferred face-to-face interaction with instructors and other students. Difference between the groups was significant: t=2.70, df = 34, p< .01. ***This is something we do not have a fix for yet with the online program***.;

ii) The WRAMC group felt that they knew the instructor and other students better than did the rural PA group. Not surprisingly, the online students had little to no knowledge of or interaction with other nurses taking the online course. The difference between the groups was large and highly significant: t=7.75, df=34, p<0001;

iii) Both groups felt that material presented met their professional needs. There was no difference between the 2 groups on this measure. Means were very close and highly positive. ***This is what we would hope to see in a comparison of two approaches in which we are hoping for non-inferiority of the new approach.;***

iv) Both groups were highly satisfied with the content of the course and were likely to take a similar course in the future (the groups did not differ);

v) Both groups performed significantly better on the knowledge (pre and post-test) scores after taking the course [F(1, 34) 48.24, p < .001]. There was no significant difference between the in-class and on-line scores and both groups increased about equally (i.e., no significant interaction).

Dr. Grady also conducted a focus group of the PA study participants who did the online course. This is her summary:

The group opened discussion with favorable comments about the experience in general. They all felt that the course was very comprehensive and covered all areas of diabetes (peds, geriatric, maternity, etc).
They all felt that the course brought to light how outdated their knowledge was about diabetes. Even the RNs that worked for the diabetes institute felt they learned a lot, especially about the medications. They commented that our area was behind in diabetes pharmaceuticals.

Other positive input included an appreciation of being able to work at their own pace and have the ability to go back over material for review and/or to take notes.

They all liked being able to see the speaker. They felt better connected if they saw the speaker at the beginning of each module. There were several modules that did not show the speaker at any time, which they did not like.

They were all in agreement about the last module; the health assessment. They did not like it and felt it was very deficient. The speaker mainly talked through it while the "patient" just sat there with little or no participation looking uncomfortable. They felt this module was disappointing after going through all the other modules which they felt were very informative and detailed. None of them felt they learned anything from this module.

They all felt that the pharmaceutical module was a lot of information to absorb. One girl described it as overwhelming. They all said it would have been nice to hear the brand names of the drugs; not just the generic names because they rarely hear or work with generic names. Many of them said they had to look up the brand names which gave them a better understanding. A couple of the girls felt the pharmaceutical module may have been too detailed.

One drawback that they all agreed on was that the classroom participants would ask questions which were not audible. They would hear the answers or explanations that the speaker gave, but didn't hear the question which was very frustrating. They said the speaker should have repeated the question before answering it.

There was some discussion about the content of the online course and whether it covered the pre/post test questions. The group was split 4 to 3 that there were questions asked on the tests that were not explained or covered in the content.

None of the RNs in the focus group experienced any technical difficulties while taking the course.
Summation:

Positive:

1. Content of the course was very comprehensive.
2. The speakers/presenters did an excellent job. They had very clear and understandable delivery and it was obvious they were expert in their field (exception; health assessment).
3. Had plenty of time (10 weeks) to complete the course.
4. Could work at their own pace.
5. Could review any of the material as much as they liked.
6. Could apply knowledge in their work (patient population).
7. Appreciated the incentives to participate/complete the course (CE credits and Sheetz gift card to cover gas for the pre/post test).
8. Format of the course was easy to access and follow. No technical difficulties.

Negative:

1. Missed visual of the speakers (only 2 of the speakers were seen briefly; Dr. Walker and Dr. Vigersky plus the health assessment nurse).
2. No interaction.
3. Couldn't ask questions.
4. Didn't like the last module; health assessment. No useful knowledge gained.

5. Pharmaceuticals too detailed and used generic names.
6. Course content did not cover test questions 100%.
7. Could not hear the questions that the classroom participants were asking.

Suggestions for future success:

1. Repeat classroom questions before giving answers/explanations.
2. Email a reminder every two weeks how much time they have left to complete the course.
3. Show the speaker at the beginning of each module and post their picture with credentials and short bio on index page.

Motivation for participating:

1. CE credits
2. Wanted to update their diabetes knowledge
3. Reputable sources: Walter Reed Army Medical Center Diabetes Institute and Mount Aloysius College
4. Convenient
5. Gift card to cover gas

All RNs expressed a very positive experience and would definitely participate in future offerings.

We do not expect to publish the results of this study. Rather, they are to be translated directly into our educational practices. ***There are no next steps for this project.***

b. Task/objective regarding Video Cell Phone Reminders – to determine if a video cell phone reminder system will improve compliance and glycemic control in patients with diabetes mellitus

Control of blood sugar has been shown in multiple studies to reduce the incidence of diabetes complications (Diabetes Control and Complications Trial Research Group, 1993; United Kingdom Prevention of Diabetes Study, 1998). Many people with diabetes struggle to achieve and maintain good glycemic control despite numerous new medications and technologies. There are numerous challenges to accomplishing appropriate control and various approaches to doing so.

The use of self blood glucose monitoring and techniques to improve medication compliance are among the more “non-invasive” methods that have been associated with improvement in diabetes management. Self blood glucose monitoring and medication adherence are each associated with improved glycemic control and reduction in adverse outcomes in both type 1 and in type 2 diabetes. For example, each additional blood glucose measurement results in a decrease in A1c of 0.32% (Schutt et al., 2006). Also, there is a lower rate of fatal and non-fatal cardiovascular events in those who self-monitor their blood glucose (Martin et al., 2006). With respect to medication adherence, once study found that for every 10% increment in drug adherence on a continuous scale resulted in a 0.6% improvement in A1c (Schectman et al, 2002). However, another study found that 27% of patients on 1 or more meds were non-adherent with their drug regimen, resulting in higher A1c’s (Krapek et al., 2004). Despite the evidence in favor of these relatively non-invasive methods for achieving diabetes control, patient adherence to self-monitoring and medications is not consistent with providers’ recommendations; e.g., 23% of patients with type 1 diabetes are non-adherent (Cramer and Pugh, 2005).

To address this, we conducted a study examining the clinical efficacy of video-based, diabetes/tips reminders, delivered daily via cell phone, on A1c, medication adherence, self-monitoring of blood glucose, and various psychosocial outcomes.

We have completed this task/objective. Specifically:

1) We drafted a protocol and obtained local and federal IRB approval. The study was a one-year, prospective randomized trial, with the active intervention during the first 6 months. Patients with poorly-controlled Type 1 or Type 2 diabetes (i.e., A1c $\geq$ 8.0%) were recruited from the outpatient clinics of the Diabetes Institute in the Walter Reed Health Care System.

To be eligible for the study, patients had be at least 18 years of age, had to have received care from a Nurse Practitioner (NP) of the Diabetes Institute for at least six months and still be poorly controlled, and had to be taking oral hypoglycemic medications and/or insulin. Patients who were pregnant, lactating, planning to become pregnant, without reliable contraception, or using glucocorticoids, amphetamines, anabolic, or weight-reducing agents were excluded.

Recruitment took place from November 2007 to February 2009. Study staff examined the appointment schedules of the Diabetes Institute's NPs for upcoming appointments and determined the eligibility of these scheduled patients by looking in the electronic medical record. Study staff then contacted all eligible patients by phone or in person to describe the study. All eligible and interested patients provided written informed consent.

Following enrollment, participants were randomized to receive 'usual care' or video messages daily from their own NP. The study used block randomization, which assumed the ratio of active intervention to control was balanced.

Six NPs created 540 30-60 second videos covering self-care topics outlined by the American Association of Diabetes Educators (AADE) – e.g., healthy eating, being active, monitoring, etcetera. Videos of the patients' NP were sent in random order, at the time of day determined by the participants after randomization. Each video could be viewed multiple times throughout the 24-hour period before the next video was sent.

All enrolled participants received a broadband-enabled cell phone and service for six months, paid for by the study.

Part of this project was conducted under funds that went to the TRUE Research Foundation. The bulk of the project was later conducted under the funds that when to HJF for this grant.

2) 65 participants enrolled in and completed the 12-month study. This sample size was sufficient to detect a decline in A1C of 1.0% (with a standard deviation of 0.90) in the treatment group of 0.50% (with a standard deviation of 0.40) in the usual care group, assuming power is 0.80 and alpha is 0.05. Note that the study had planned for smaller within-group declines in A1C and smaller between-group differences, so the sample size estimate was larger, but interim analyses of A1C change and funding constraints pointed to stopping recruitment at 65.

3) We analyzed the data and found Both groups experienced declines in A1c. For the video messages group, mean [standard deviation (SD)] decline in A1c from baseline was 1.2% (1.8%), 1.1% (2.3%), 1.2% (2.2%), and 1.3% (1.8%) at 3, 6, 9, and 12 months, respectively. For the usual care group, it was 0.4% (1.2%). 1.1% (1.6%), 1.1% (1.7%), 0.9% (1.6%) at 3, 6, 9, and 12 months. Post-hoc

analyses of covariance (ANCOVA) indicated that the two groups' change in A1c from baseline to 3 months, with the baseline A1c included, was significantly different ($p = 0.02$).

The rates of change in A1c over 12 months were significantly different from zero for both treatment groups after controlling for A1c level at the time of enrollment, age, gender, and type of diabetes [(a) $p < 0.002$ for time*usual care and $p = 0.01$ for time*time*usual care and (b) $p = 0.002$ for time*video messages and $p = 0.004$ for time*time*video messages]. The 12-month, adjusted rate of change was greater at all time points for the video messages group, but the group differences were modest -- about 0.1% to 0.2% per time point, with a cumulative decline in A1c at 12 months of 1.2% for the video message group and 1.0% for the usual care group. Age was also significant; i.e., older age was related to decreasing A1c. Gender and type of diabetes were not significant.

Analysis of A1c by viewership found that the consistent viewers experienced the greatest improvement. Mean (SD) A1c decline between baseline and 6 months -- the period of time in which decline was greatest -- was 0.8% (2.2%) for the subjects in the early cessation group, 0.6% (1.4%) for the intermittent viewers, and 1.9% (3.1%) for the persistent viewers. As of 12 months, mean (SD) A1c decline from baseline for the subjects in the early cessation group was 1.1% (1.9%), 1.3% (1.3%) for the intermittent viewers, and 1.7% (2.4%) for the persistent viewers.
The changes suggested by the means were supported by more complicated, "adjusted" statistical models; i.e., 12-month rate of change in A1c was significant for the early cessation group ($p < 0.001$ for time*cessation group and $p = 0.004$ for time*time* cessation group) and the persistent viewers ($p < 0.001$ for time*persistent group and $p < 0.001$ for time*time*persistent group), and the cumulative, adjusted decline over 12 months was 0.6% greater for the persistent viewership group than for the early cessation group.

The study groups did not differ in terms of whether they provided SMBG data or the amount of hyperglycemia (> 180 mg/dl or > 240 mg/dl) identified by those data. Hypoglycemia (< 70 mg/dl) was slightly more frequent for the video messages group ($p = 0.05$ for both time ranges). Further analyses of hypoglycemia indicate that the highest frequency of hypoglycemic readings was observed for the subjects in the group that did not view the videos ('early cessation group'). There were no significant within-group changes in SMBG metrics over time.

Weight and BP did not change during the study period.

4) We published the results. The citation is: Bell AM, Fonda SJ, Walker S, Schmidt V, Vigersky RA. Mobile phone-based video messages for diabetes self-care support. *Journal of Diabetes Science and Technology* 2012;6(2):310-319.

There are no next steps for this project.

c. Task/objective regarding the Deployment of a Telehealth Eye Care Program in rural PA – to deploy this program in clinics in the 12th Congressional District of PA with links to a central reading station at WRAMC

Diabetic eye disease is the leading cause of blindness among working-age adults, yet it is largely preventable with timely diagnosis and treatment (Diabetic Retinopathy Study Research Group, 1981; Early Treatment Diabetic Retinopathy Research Group, 1991). Diabetes-related vision loss is often caused by a combination of poor access to and compliance with periodic eye examinations that target early detection of sight-threatening eye disease. Even in settings with little or no financial barriers to health care, compliance with periodic eye examinations is suboptimal. For example, annual compliance with eye examinations among diabetic patients is 53%, 67.7%, and 52.2% in the Indian Health Service, Department of Veterans Affairs,

and the Department of Defense health care systems (Indian Health Service, 2000; Department of Veterans Affairs, 2000; Department of Defense, 2000). We suspect these rates are worse in geographical regions, such as rural PA, where access to care is more difficult.

To address this problem, we have planned to bring a telehealth eye care program to rural PA. The program was originally developed at the Beetham Eye Institute. This program and those modeled after it are well-described and validated (Aiello et al., 1998; Cavallerano AA et al., 2003; Cavallerano JD et al, 2005; Bursell et al., 2001; Chow et al., 2006). For diagnosis of diabetic retinopathy and diabetic macular edema, the telehealth eye care assessments agree substantially with mydriatic seven-standard field Early Treatment Diabetic Retinopathy Study (ETDRS) protocol photography (Bursell et al., 2001) and with dilated clinical examinations by retina specialists (Cavallerano JD et al., 2005). For diagnosis of nondiabetic eye disease among people with DM, the telehealth eye care assessments agree substantially with dilated clinical examinations by retina specialists (Chow et al., 2006). The Principal Investigator of this grant has validated the telehealth eye care program in both a single clinic and multi-clinic setting, the latter utilizing a hub-and-spoke design with cameras deployed in satellite clinics and a central reading facility at a tertiary care facility; Ahmed and colleagues have shown the telehealth eye care program to be nearly 100% sensitive and specific in the two-thirds of images that are technically capable of being graded (Ahmed et al., 2006). The telehealth diabetes eye care program has also been shown to have better diagnostic and clinical outcomes at lower costs compared to conventional clinic-based eye examinations when used to detect sight-threatening proliferative diabetic retinopathy in the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs (Whited et al., 2005). In addition to being clinically valid and cost-effective, the telehealth eye care program increased patient adherence with recommended standards of care for periodic eye examinations and follow-up treatment (Davis et al., 2003; Conlin et al., 2006; Wilson et al., 2005) and was found to be associated with decline in A1c and lipid levels over time (compared with standard care not involving the telehealth eye care program) (Fonda et al., 2007).

We have experienced many difficulties with this task/objective. We have accomplished much, but then have had insurmountable obstacles that led to changes in our Statement of Work. Below we summarize where we have been and where the project is NOW going. In brief, we,

1) Sought to enlist clinics in PA to participate in a randomized controlled trial of the program. We attended 4 meetings, one of which was with the Medical Director of the largest health care provider in the area (Conemaugh Health System). Although initially expressing interest, physicians in that area have refused to participate. They did not agree with substituting the telehealth program for an annual dilated exam (which would be a requirement of a randomized controlled trial) and they were concerned that supporting such a program would adversely affect their revenue by taking patients away. Their refusal forced us to rethink the original research plan.

2) **(**Since physicians in PA were not willing to conduct a randomized controlled trial of the telehealth eye care program) we developed a new deployment and evaluation plan. We planned a pre-/post-test of the deployment as before, but the deployment involved participating in health fairs and weeklong screenings throughout that targeted geographical area, rather than integrating into a clinic. All people with diabetes who have no prior history of diabetic retinopathy would have been eligible, and we planned to screen them and provide education in the public health-oriented format of the health fair. We also planned to follow study participants over time. This approach is novel and has a public health focus. ***NOTE: We are still planning this type of approach. See below.***

3) Submitted a revised Statement of Work which was approved.

4) Identified 2 local sites willing to participate in weeklong "fairs" or screenings, as well as a local collaborator to assist us. We have also identified an Ophthalmology practice in the area where we will, if necessary, be able to refer study/screening participants who are found to have diabetic

retinopathy during the screening. This was a challenge because it is still the case that most telehealth eye care programs take place in fixed locations, namely clinics.

5) Received IRB approval at the local level.

6) Lost our local champion in rural PA (Dr. Grady), where the study was to be conducted. She no longer had an affiliation at the local college where the study received local approval. As important, the federal reviewer identified several large obstacles to this approach; in particular, it would have required local approval at each site we did a fair!

7) Discussed on the telephone with Mr. Robert Read -- and then submitted another revision to the Statement of Work -- a plan to conduct the study in a socioeconomically disadvantaged area within Washington, DC. This change would allow us to submit the protocol to a local IRB, together with someone we are working with locally, and to carry out the exact same study design as previously described in the earlier Revision to the Statement of Work (see 2 above). We will be able to complete the eye screenings ourselves, using our existing equipment. The spirit of the protocol will remain the same; i.e., to deploy a public health-oriented telehealth intervention that can identify and prevent diabetic retinopathy in an at-risk, underserved population. ***This change was approved in October 2011 and we were notified in November.***

8) Obtained the state-of-the art nonmydriatic camera (for free) for doing this study. Also trained Ginger Schmidt (who is on this study) in its use.

9) Developed the eye education component of the study, which will be given to each study participant.

10) Identified local champions at Washington Hospital Center, who can submit the protocol to their IRB.

In the coming year, we plan to submit the protocol to Washington Hospital Center for local IRB approval, then to HRPO. We can then conduct the study. Between now and when we obtain federal approval, Dr. Fonda and Ms. Schmidt will be participating in a health fair (***not as part of this study***) to practice/pilot the imaging technique and education (May 2012). This experience will inform the study when we are approved to do it.

This is our last task/objective for the CMICD project, so we are eager to complete it.

d. Task/objective regarding the Use of the Comprehensive Diabetes Management Program (CDMP) by Primary Care Providers – to supply providers in rural PA with CDMP, an interactive, modular, web-based care- and self-management tool for physician, care managers and patients

The CDMP is an interactive, modular, web-based tool for physicians, care managers, and patients, designed to a) provide a high level of continuous care and communication between patients, care managers, and physicians, b) draw on the latest clinical guidelines and guide care managers and physicians in following them, c) focus on patients' clinical and behavioral problem areas, and d) increase the role of the diabetes patient in the care planning process and management. Among the CDMP's modules are the Behavior Assessment Tool (BAT), which is a questionnaire designed to assess patients' barriers to effective diabetes care, and two Nutrition Assessment Tools (NAT-A and NAT-B), which are intended to assess why people eat certain ways. The CDMP also has an overall risk stratification algorithm, which uses a variety of data drawn from the patient's record (such as lab values, blood pressure readings, smoking status, whether or not the patient had a particular exam, etc.) to indicate how the patient compares to established goals in the areas of glycemic control, nephropathy, peripheral vascular disease, peripheral neuropathy, and retinopathy. The

CDMP was developed after the aforementioned telehealth eye care program, because it is well-known that prevention and appropriate management of diabetic retinopathy requires good care- and self-management of diabetes overall. The telehealth eye care program is integrated into the CDMP.

As with the telehealth eye care program, the original study was proposing an evaluation of the quality of diabetes care pre- and post-implementation of the CDMP. The challenges encountered for the above apply to this project as well. Further, the change in scope approved in the revised Statement of Work applies here as well.

e. Task/objective regarding the Use of a Computer-Assisted Decision Support (CADS) System to improve glycemic control -- to deploy CADS to primary care providers in a pilot study as a proof-of-concept study

Due to the complexity of diabetes, its co-morbidities such as hypertension and hyperlipidemia, and the seriousness of its complications, people with diabetes are usually best monitored by highly skilled health care professionals who are equipped with the latest information to help ensure early detection and appropriate treatment and to provide diabetes education to patients. But due to a dearth of endocrinologists in both military and civilian health care settings, primary care providers (PCPs) (including family practitioners, nurse generalists and physicians' assistants) provide care to the vast majority of patients with diabetes who are not necessarily equipped with the latest information. And in a healthcare environment where a shortage of Certified Diabetes Educators exists, especially in rural areas, the burden of diabetes education often falls on staff registered nurses in hospitals, physician offices, and other healthcare facilities who may lack the expertise and/or time to provide this service. It is imperative, therefore, to give these providers the advanced technology and health information management tools to support effective care management.

To transfer this knowledge to PCPs, the Principal Investigator developed a series of rules-based algorithms to provide decision support to primary care providers for the management of their patients with diabetes. We call it a Computer-Assisted Decision Support (CADS) System. The software allows for: download of patient self-monitored blood glucose data from memory meters to a central database; display of the data in tabular and graphical form; generation of descriptive statistics; assessment of overall level of control; and evaluation of hypoglycemia and hyperglycemia. A numerical score synthesizing all of the elements of good control is computed and presented. The software identifies a series of potential problems and prioritizes them (e.g. overnight hypoglycemia, hypoglycemia at other times of day, hyperglycemia, excessive postprandial excursions, etc.). The programs then identify the most appropriate change(s) needed in therapy involving oral or injectable regimens for type 2 diabetes, alone or in various combinations. The program indicates which dose or doses of medications should be increased or decreased, when there has been 'failure' of a regimen to provide an adequate level of control consistent with goals for A1c and glycemic levels, and also provides recommendations for moving to another regimen.

After the first version of the CADS System was developed, we determined that we should integrate it with the CDMP so as to facilitate remote patient upload of their self-monitored blood glucose data and to provide the CADS System with as much background information about each patient as possible.

At the beginning of the funding period for this grant, the original software developer, Health Sentry, did not release the required software code to us as scheduled, seriously delaying the integration of CADS with the aforementioned CDMP. The need to integrate with CDMP means we need additional time and a Revised Statement of Work. **We submitted a Revised Statement of Work and it was approved. The integration has now been accomplished.**

In a user evaluation of the CADS System by a Nurse Practitioner in our clinic, we found that the system was not yet ready for circulation to PCPs. In response, we developed the interface more fully, we devised an

improved process for collecting the patients' self-monitored blood glucose data, and we created new, more user-friendly graphs of the self-monitored blood glucose data. Also, new medications for diabetes have been added to the market since the drafting of the original rules and algorithms for the CADS System, so we expanded the application to include those. We additionally developed new use cases, which we discovered as part of the user feedback process. The new use cases ensure that the CADS System is more accurate and complete. Lastly, we wrote a protocol for a full testing of the application (to be performed under separate funding) and developed a Technical Assessment Questionnaire to be administered to providers using the application.

Per the Revised Statement of Work, the outstanding deliverable is now a vetted (with respect to usability and accuracy) CADS System.

No further work is due on the CADS System as part of this grant.

Key Research Accomplishments

Virtual Education Techniques:

- Completed construction of computer and video-teleconferencing lab at Mount Aloysius
- Scheduled the workshop events
- Completed protocol draft and submitted to IRB
- Completed workshop agenda at Walter Reed
- Developed interactive web site for all of the course content and quizzes
- Conducted 3 workshops and enrolled study participants
- Completed analyses and presented results in this report
- Completed a focus group and presented results in this report

Video Cell Phone Tips/Reminders:

- Created an extensive library of videos
- Drafted protocol, submitted it to the IRB, and received approval
- Recruited 65 subjects and completed the protocol with them
- Conducted analyses of the outcomes
- Published a peer-reviewed paper of our results in the *Journal of Diabetes Science and Technology*

Telehealth Eye Care Program and Comprehensive Diabetes Management Program:

- Met with health care providers and Medical Directors to enlist clinics to participate – which led to rethinking the methodology
- Contracted to buy the equipment needed (but eventually obtained better, free equipment – see below)
- Identified local champions in PA
- Identified and enlisted local sites for a public health-type "fair" or screening
- Established the new methodology by which we will conduct the study
- Drafted a protocol
- The protocol was approved by the local IRB and now we are preparing a response to the federal IRB
- Lost our local champion and revised the plan to do the same study in a socioeconomically disadvantaged area in Washington, DC
- Identified new local champions in DC
- Obtained a few Canon system to be used for this project
- Drafted educational material on eyes and diabetes, for the screening study

Computer-Assisted Decision Support System:

- Developed the interface and how we are going to collect the data so that the application can perform its tasks
- Through user feedback process, discovered/developed additional use cases
- Developed a Technical Assessment Questionnaire to be administered to providers observing the application
- Wrote a protocol for a full test under new funding
- Created new and improved graphs of the self-monitored blood sugar data
- Completed integration of the system with CDMP

Reportable Outcomes

The following are presentations we have given to date and include some information from these projects:

- Vigersky R, Bell A, Fonda S, Sami S, Walker S, Schmidt V. Using cell phone reminders in diabetes mellitus. Abstract. *Telemedicine and e-Health* 2009; 15: S31.
- Fonda SJ. A cell phone intervention for improving adherence to diabetes therapy. Presented at the US Army Telemedicine Partnership Series 2010. mHealth: The use of cell phones for Healthcare Applications. Annual Meeting of the American Telemedicine Association, May 2010.
- Fonda SJ. "e-, i-, or m-health? Blurring Boundaries between Provider and Patient-Centered Management". Annual Meeting of the Diabetes Technology Society, November 13, 2010.
- Bell AM, Fonda SJ, Walker S, Schmidt V, Vigersky RA. Mobile phone-based video messages for diabetes self-care support. *Journal of Diabetes Science and Technology* 2012;6(2):310-319.

The following are projects that we have applied for funds to support. Aspects of these projects have grown out of what we have learned conducting this project. In brief, the projects will:

- Develop and study a Personal Health Record Application (PHR-A) that captures information about daily living important for diabetes & provides decision support with actionable advice for diabetes self-care
- Develop a self administered stereo non mydriatic automated retinal camera (SNARC) containing automated retinal lesion (ARL) detection using adaptive optics
- Study the use of a Computer-Assisted Decision Support (CADS) system to improve outcomes in patients with Type 2 Diabetes who are treated by Primary Care Providers.

Conclusion

The CMICD is an ongoing, multi-project effort and as yet we do not have final research and development results to report for all of the projects; several are close, however, including the Video Cell Phone Study, the Virtual Nursing Education Study, and the Computer Assisted Decision Support System development effort.

We believe that the projects herein have the potential to address and/or prevent the serious complications of diabetes, even in geographical regions or socioeconomic settings where access to diabetes education and/or care are limited. One such project can reduce or prevent complications through the use of diabetes tips and reminders sent via a relatively low-cost, ubiquitous and familiar tool, the cell phone. Another project can do so through the combination of telemedicine technologies and public health-based education to provide a quick, convenient, and low-cost evaluation for diabetic retinopathy. The evaluation for diabetic retinopathy can then lead to a care management plan based in best practices guidelines, using our medical informatics tool, the CDMP. Yet another project can mitigate diabetes complications with the development and distribution of diabetes expertise – as computer-assisted decision support – to providers who are generalists

and/or do not have the time to stay apprised of the many and varied drug regimens for diabetes management. Finally, with the CMICD, nurses in rural areas who care for patients with diabetes but do not have access to or time-flexibility for diabetes-specific continuing education can now receive this education through the Internet, at their own pace and while continuing to work. Although the content of the tips, decision support, education, and clinical guidelines is all about diabetes, the approaches here can easily be applied to other chronic diseases.

References

Ahmed J, Ward TP, Bursell S-E, Aiello LM, Cavallerano JD, Vigersky RA. 2006. The sensitivity and specificity of nonmydriatic digital stereoscopic retinal imaging in detecting diabetic retinopathy. *Diabetes Care* 29:2205-2209.

Aiello LM, Bursell SE, Cavallerano J, Gardner WK, Strong J. 1998. Joslin Vision Network Validation Study: pilot image stabilization phase. *Journal of the American Optometry Association* 69:699-710.

Bursell SE, Cavallerano JD, Cavallerano AA, et al. 2001. Stereo nonmydriatic digital-video color retinal imaging compared with Early Treatment Diabetic Retinopathy Study seven standard field 35-mm stereo color photos for determining level of diabetic retinopathy. *Ophthalmology* 108:572-585.

Cavallerano AA, Cavallerano JD, Katalinic P, Tolson AM, Aiello LP, Aiello LM. 2003. Use of Joslin Vision Network digital-video nonmydriatic retinal imaging to assess diabetic retinopathy in a clinical program. *Retina* 23:215–223.

Cavallerano JD, Aiello LP, Cavallerano AA, et al. 2005. Nonmydriatic Digital Imaging Alternative for Annual Retinal Examination in Persons With Previously Documented No or Mild Diabetic Retinopathy. *American Journal of Ophthalmology* 140:667-667.

Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2008.

Chow SP, Aiello LM, Cavallerano JD et al. 2006. Comparison of Nonmydriatic Digital Retinal Imaging versus Dilated Ophthalmic Examination for Nondiabetic Eye Disease in Persons with Diabetes. *Ophthalmology* 113:833-840.

Conlin PR, Fisch BM, Cavallerano AA, Cavallerano JD, Bursell SE, Aiello LM. 2006. Nonmydriatic tele-retinal imaging improves adherence with annual eye examinations in patients with diabetes. *Journal of Rehabilitation, Research and Development* 43:733-740.

Cramer JA, Pugh MJ. 2005. The influence of insulin use on glycemic control. *Diabetes Care* 28:78-83.

Davis RM, Fowler S, Bellis K, Pockl J, al Pakalnis V, Woldorf A. 2003. Telemedicine improves eye examination rates in individuals with diabetes. A model for eye-care delivery in underserved communities. *Diabetes Care* 26: 2476.

Department of Defense administrative data for ophthalmoscopy examination rates among patients with diabetes mellitus. 2000.

Department of Veterans Affairs administrative data for ophthalmoscopy examination rates among patients with diabetes mellitus. 2000.

Diabetes Control and Complications Trial Research Group. 1993. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *New England Journal of Medicine* 329:977-986.

Diabetic Retinopathy Study Research Group. 1981. Photocoagulation treatment of proliferative diabetic retinopathy. Clinical application of Diabetic Retinopathy Study (DRS) findings, DRS Report Number 8. The Diabetic Retinopathy Study Research Group. *Ophthalmology* 88:583-600.

Early Treatment Diabetic Retinopathy Study Research Group. 1991. Early photocoagulation for diabetic retinopathy. ETDRS report number 9. Early Treatment Diabetic Retinopathy Study Research Group. *Ophthalmology* 98:766-785.

Fonda SJ, Bursell, SE, Lewis DG, Garren J, Hock K, Cavallerano J. 2007. The relationship of a diabetes telehealth eye care program to standard eye care and change in diabetes health outcomes. *Telemedicine and e-Health* 13:635-644.

Indian Health Service audit data for ophthalmoscopy and Joslin Vision Network examination rates among patients with diabetes mellitus. 2000.

Krapek K, King K, Warren SS, George KG et al. 2004. Medication Adherence and Associated Hemoglobin A1c in Type 2 Diabetes. *Annals of Pharmacotherapy* 38:1357-1362.

Martin S, Schneider B, Heinemann L et al. 2006. Self-monitoring of blood glucose in type 2 diabetes and long-term outcome: an epidemiological cohort study. *Diabetologia* 49:271–278.

PharmaLive.com. Accessed at http://www.medadnews.com/News/Index.cfm?articleid=678317, 14January2010.

Schectman JM, Nadkarni MM, Voss JD. 2002. The association between diabetes metabolic control and drug adherence in an indigent population. *Diabetes Care* 25: 1015-1021.

Schutt M, Kern W, Krause U, Busch P, Dapp A et al. 2006. Is the frequency of self-monitoring of blood glucose related to long-term metabolic control? Multicenter analysis including 24 500 patients from 191 centers in Germany and Austria. *Exp Clin Endocrinol Diabetes* 114: 384–388.

United Kingdom Prevention of Diabetes Study: Prospective Diabetes Study Group. 1998. Intensive blood glucose control with sulfonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes: UKPDS 33. *Lancet* 352:837-853.

Whited JD, Datta SK, Aiello LM et al. 2005. A modeled economic analysis of a digital teleophthalmology system as used by three federal healthcare agencies for detecting proliferative diabetic retinopathy. *Telemedicine and e-Health* 11:641-651.

Wilson C, Horton M, Cavallerano J, Aiello LM. 2005. Addition of primary care-based retinal imaging technology to an existing eye care professional referral program increased the rate of surveillance and treatment of diabetic retinopathy. *Diabetes Care* 28:318-322.

Appendices

None